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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,060	03/16/2001	Carl T. Wild	1900.0260001/JMC/SJE	4671
26111	7590	08/11/2006	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/809,060

Applicant(s)

WILD ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7 and 30-40 is/are pending in the application.
- 4a) Of the above claim(s) 35-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7 and 30-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 7, and 30-40 are pending in the application.
2. In the prior action, the Final action mailed on March 27, 2006, claims 1, 7, and 30-40 were pending, with claims 35-40 withdrawn from consideration; and claims 1, 7, and 30-34 under consideration and rejected.
3. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 26, 2006 has been entered.

In the Response accompanying the RCE, the Applicant amended claims 1, 7, and 30-33.

4. Currently, claims 1, 7, 30-34 are under consideration.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **(Prior Rejection- Withdrawn)** Claims 1 and 31 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it was unclear if the claims were intended to read on compositions comprising fragments of the indicated complex, or if the claims were directed to complete forms of the gp41/gp120 complex. In view of the amendments to the claims, the rejection is withdrawn.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **(Prior Rejection- Maintained)** Claims 1, 7, and 30 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims were rejected to extent that they read on embodiments of the claimed composition wherein the stabilizing peptides may be fragments of the identified stabilizing peptides.

The Applicant traverses the rejection on the basis that those in the art could easily identify fragments of the indicated peptides by identifying the N- and C- terminal amino acids subject to deletion. This argument is not found persuasive.

This is because the claimed invention does not require merely a fragment of the stabilizing peptide, but fragments thereof that act as a stabilizing peptide (i.e. that bind to the gp41/gp120 complex and stabilize it). While, as the Applicant indicates, the application discloses fragments of the stabilizing peptide of SEQ ID NO: 1 (which, it is noted, is no longer in the claims), the application does not identify fragments thereof that act as stabilizing peptides. Moreover, as was indicated in the prior actions, there is uncertainty in the art as to which fragments of the indicated peptides would in fact have the required functional activities. Thus, the mere act of identifying the N- and C- terminal amino acids of the peptides is not sufficient to demonstrate possession of the claimed invention because the identification of such residues is

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not sufficient to identify fragments of the indicated peptides that would maintain the functional characteristics of a stabilizing peptide according to the claimed inventions.

Moreover, it is further noted that, while those in the art may screen the indicated peptides for the required activity, the ability of those in the art to conduct such screening does not suffice to provide descriptive support for peptides that may be identified through use of such a screening assay. See e.g., *University of Rochester v. G.D. Searle & Co.*, 69 U.S.P.Q. 2d 1886, at 1895 (CAFC 2004)(stating that the identification of a screening assay for the identification of a biomolecule is not the same as disclosing the specific biomolecule, and that it is the identification of the specific biomolecules which is required). See also, MPEP § 2163 II.A.2(a). For these reasons, and the reasons of record, the Applicant's arguments are not found persuasive, and the rejection is maintained.

9. **(Prior Rejection- Withdrawn)** Claims 1, 7, and 30-34 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed compositions wherein the envelope protein is an human immunodeficiency virus (HIV) gp41/gp120 complex, does not reasonably provide enablement for the claimed compositions wherein the envelope protein is any gp41/gp120 complex. In view of the amendments to the claims limiting the complex to the HIV gp41/gp120 complex, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **(Prior Rejection- Maintained)** Claims 1, and 31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Furuta et al. (Nat Struct Biol 5: 276-79) in view of Wild et al., (PNAS 91:9770-74) (both references of record in the March 2001 IDS). The Applicant has amended the claims to indicate that the claimed compositions are “suitable to elicit production of an antibody which binds to the fusion-active form of HIV gp41/gp120 complex, and thereby inhibits the fusion of gp41/gp120 complex with the membrane of a target cell.” The Applicant traverses the rejection as applied against the amended claims on the basis that the art reference does not teach such a use. This argument is not found persuasive.

The Applicant is asserting that the claimed products are non-obvious on the basis of a new intended use for the claimed composition. However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the present case, there is no argument by the Applicant that the intended use implies such a structural distinction, nor any apparent difference between the claimed composition and the compositions suggested by the art. The Applicant’s argument in traversal is therefore not found persuasive. The rejection is therefore maintained for the reasons of record, and the reasons above.

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12. **(Prior Rejection- Maintained)** Claims 1, 7, and 30-34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Furata in view of Wild as applied to claims 1 and 31 above, and further in view of Haddrick et al. (J Virol Methods 61:89-93). The Applicant traverses this rejection on the same basis as was asserted with respect to the rejection of claims 1 and 30 over the teachings of Furata and Wild above. For the same reasons as indicated above, the argument is not found persuasive, and the rejection is maintained.

Conclusion

13. No claims are allowed.

14. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

Jiang et al., J Virol 72: 10213-17. This reference is drawn to a related art, but does not teach or suggest the presently claimed invention.

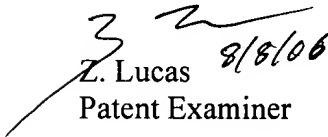
Haynes et al., U.S. 7,033,593. This reference appears to read on similar subject matter to the present claims. However, the reference does not qualify as prior art against the present application.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner